HON. JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

B. E. and A. R., on their own behalf and on behalf of all similarly situated individuals, Plaintiffs, v. DOROTHY F. TEETER, in her official capacity as Director of the Washington State Health Care Authority, Defendant.	NO. 2:16-cv-00227 PLAINTIFFS' MOTION FOR CLASS CERTIFICATION **Noted for Consideration: April 15, 2016**

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Table of Contents

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I. INTRODUCTION

Plaintiffs are Washington Medicaid enrollees who are living with a communicable, chronic inflammatory disease caused by infection of the Hepatitis C virus ("HCV"). More than 20,000 people in the United States die each year due to liver disease caused by HCV, and it remains the most common cause for liver transplants in the United States. *See* Declaration of Robert Gish, M.D. ("Gish Decl."), ¶ 3. Fortunately, the FDA has approved certain Direct Acting Antiviral ("DAA") drugs – FDA-designated "breakthrough" pharmaceutical treatments with effective cure rates approaching 100%. *Id.*, ¶ 7. The prevailing clinical standard of care recommends DAA treatment for nearly everyone living with HCV, regardless of the extent to which the virus has already damaged their body. Gish Decl., ¶ 8. For the first time since the Hepatitis C virus was discovered, there is a curative treatment that could eradicate the disease entirely.

Despite the promise of the new DAA medications, the Washington Health Care Authority (WHCA), has limited access to the cure. On February 25 2015, WHCA issued an exclusionary coverage policy for DAA treatment ("WHCA Policy"). *See* Dkt. No. 1-1. The WHCA Policy *denies* coverage for DAA treatment for all Washington Medicaid enrollees infected with HCV, except those whose livers exhibit severe scarring, or those with slightly less liver damage who are co-infected with other severe ailments. *Id.* In effect, Washington's policy tells members of the putative class that it will not provide coverage to cure their devastating chronic illness until they have become so sick that irreversible damage has been done to their body. Gish Decl., ¶ 17. To make matters worse, WHCA officials have baldly admitted this rationing of care is based on political and budgetary concerns, rather than on medical evidence. Donna L. Sullivan, M.S.,

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Pharm.D., WHCA's Chief Pharmacy Officer, publicly admitted that fiscal and political issues were behind the rationing policy:

> ***I can guarantee you that all of us agree that everyone should be treated*** whether they are at stage 2, stage 3, stage 4. However, we have received funding only based on the criteria that we gave for F3. … ***It's out of our hands. None of us would argue that we should not expand it***, that it's not the right thing to do, but we live in a ***political*** environment as a state that I have to operate within the resources and rules around those resources that have been given to us.

Declaration of Eleanor Hamburger., *Exh. B,* p. 64 (emphasis added).

The WHCA Policy conflicts not only with the Medicaid Act and its governing jurisprudence, but also with on-point federal agency guidance and the prevailing clinical standard of care. Hamburger Decl., *Exh. F*. The plaintiffs challenging this policy therefore move the Court for class certification for the purposes of seeking declaratory and prospective injunctive relief pursuant to Fed. R. Civ. P. 23(b)(2). Such class actions are designed to address, in a single proceeding, precisely this type of uniform and systemic violation of the law. A judicial finding that defendant's actions do not comply with the law will apply equally to all members of the proposed class. This is an ideal case for class certification. *See Dunakin v. Quigley*, 99 F. Supp. 3d 1297, 1333 (W.D. Wash. 2015).

II. FACTUAL BACKGROUND

Medicaid is the joint federal-state program designed to provide health care coverage for low-income individuals.[1] Both B.E. and A.R. are enrolled in Medicaid and have HCV. Dkt. No. 1, ¶¶ 1–2 (Complaint); Dkt. No. 16, ¶¶ 1–2 (Answer); Dkt. No. 7, ¶¶ 1–2; Dkt. No. 8, ¶¶ 1-2.

[1] Plaintiffs move simultaneously for a preliminary injunction. They incorporate herein by reference the factual summary set forth in their preliminary injunction motion.

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DAA treatment has been deemed medically necessary for them, as illustrated by prescriptions from their treating medical providers. Dkt. No. 1, ¶¶ 1–2, 28; Dkt. No. 16, ¶¶ 1-2, 28; B.E. Decl., ¶ 3; A.R. Decl., ¶ 3. Nevertheless, the defendant has denied coverage of DAA treatment pursuant to the WHCA Policy. Dkt. No. 1, ¶ 21; Dkt. No. 1-1; Dkt. No. 16, ¶ 21 ("Defendant admits that HCA has adopted a Hepatitis C Treatment Policy that is attached to the Plaintiff's Complaint as Exhibit A"). The WHCA determined that plaintiffs did not exhibit liver damage severe enough to qualify for DAA treatment. B.E. Decl., ¶ 3; A.R. Decl., ¶ 3. By delaying their treatment, WHCA needlessly exposes plaintiffs, as well as all other putative class members, to heightened risk of cirrhosis, liver cancer, heart attacks, fatigue, joint pain, depression, sore muscles, arthritis, unneeded liver transplants, jaundice, and even death. Gish Decl., ¶ 10.

It is estimated that nearly 100,000 Washingtonians are living with HCV. Hamburger Decl., *Exh. A*, p. 1. Although it is not known how many are enrolled in Medicaid, the defendant estimates that 4,700 individuals would be eligible for treatment covered by Medicaid if its policy was amended to cover enrollees with HCV with fibrosis scores of F2. *Id.* It is clear that thousands of Washington Medicaid enrollees stand to benefit from class certification .

Plaintiffs now seek to certify a class defined as:

> All individuals who:
>
> (1) were, are, or will be enrolled in Washington state Health Care Authority's Medicaid Program on or after October 10, 2014;
>
> (2) require, or are expected to require treatment for Hepatitis C with Harvoni/ledipasvir-sofosbuvir or other similar direct acting antivirals under the current guidelines adopted by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; and
>
> (3) do not meet the coverage criteria for HCV medication adopted by WHCA, as reflected in Appendix 1 to Plaintiffs' Complaint.

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The class described above meets each of the class certification criteria set forth in the Federal Rules of Civil Procedure.

III. LEGAL STANDARD

A district court may certify a class when plaintiffs meet their burden to show that all of the requirements of Federal Rule of Civil Procedure 23(a) are met, including: "(1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a). In addition to meeting the Rule 23(a) prerequisites, the party seeking class certification must also satisfy one of three categories described in Rule 23(b). *Dunakin v. Quigley*, 99 F. Supp. 3d 1297, 1324–25 (W.D. Wash. 2015); *Leyva v. Medline Indus., Inc.*, 716 F.3d 510, 512 (9th Cir. 2013). Plaintiffs here seek certification pursuant to Rule 23(b)(2) only. Certification is appropriate under Rule 23(b)(2) where the defendant has "acted on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2).

IV. ARGUMENT

A. Plaintiffs Satisfy the Strictures of Fed. R. Civ. P. 23(a).

1. The Class Is so Numerous as to Render Joinder Impracticable.

Rule 23 requires plaintiffs to show that "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). While courts have identified no bright line number of class members that satisfies this criterion, "[g]enerally, forty or more members will satisfy the numerosity requirement." *Dunakin v. Quigley*, 99 F. Supp. 3d 1297, 1326–27 (W.D.

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Wash. 2015), *quoting Garrison v. Asotin Cnty.*, 251 F.R.D. 566, 569 (E.D. Wash. 2008). Rather than focusing on a specific number, the inquiry should be directed to the question whether joinder of all potential plaintiffs would be impracticable. *See id., citing McCluskey v. Trs. of Red Dot Corp. Emp. Stock Ownership Plan & Trust,* 268 F.R.D. 670, 674 (W.D. Wash. 2010).

Plaintiffs' numerosity burden is easily satisfied here. WHCA has already denied over 900 requests by Medicaid recipients with HCV for coverage of DAAs under its exclusionary policy and estimates that if coverage were expanded to include only Medicaid enrollees with a fibrosis score of F2, an additional 4,700 Medicaid recipients would be affected. Hamburger Decl., *Exh. A*, p. 1, *Exh. D*, p. 2. *See* Dkt. No. 1, ¶ 33; Dkt. No. 16, ¶ 33 (defendant does not dispute the accuracy of this information). As a result, the class numbers in the thousands and is so large that joinder is impracticable.

2. There Are Questions Common to the Class.

Commonality lies at the core of the Court's class certification analysis, requiring the plaintiffs to identify at least one central question that will yield an answer common to the class. This commonality is what binds the class together and justifies aggregate treatment under Rule 23. This requirement is "construed permissively" and may be satisfied either by showing the "existence of shared legal issues with divergent factual predicates" or "a common core of salient facts coupled with disparate legal remedies within the class." *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1019 (9th Cir. 1998). Thus, commonality only imposes a "limited burden" upon the plaintiff given that it "only requires a single significant question of law or fact." *Mazza v. American Honda Motor Co., Inc.*, 666 F.3d 581, 589 (9th Cir. 2012).

Plaintiffs seek adjudication of a single core legal question: ***Does WHCA's uniform exclusionary criterion for DAAs in HCV-infected individuals – a criterion that denies coverage***

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of FDA-approved pharmaceuticals until significant liver damage has already occurred – violate the Medicaid Act? This key question is common to all putative class members. This question includes a number of others, all of which are likewise common to plaintiffs and the putative class:

1. Has defendant violated Title XIX of the Social Security Act (also known as the Medicaid Act) by withholding DAAs from all HCV-infected Washington State Medicaid recipients unless their liver is already irreversibly damaged by HCV? *See* 42 U.S.C. §1396a(a)(10).

2. Has defendant violated the "reasonable promptness" requirement of 42 U.S.C. §1396a(a)(8) by implementing a policy that rations coverage for Medicaid enrollees seeking HCV treatment, thereby requiring plaintiffs and the class to wait until they have developed severe liver damage before receiving curative treatment?

3. Has defendant violated the Medicaid Act's comparability requirements, 42 U.S.C. §1396(a)(10)(B)(i), (ii), by discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards? *See* 42 C.F.R. §440.240.

Commonality is manifest, and exists here beyond any reasonable doubt.

3. The Plaintiffs' Claims Are Typical of the Class.

In order to satisfy the typicality requirement of Fed. R. Civ. P. 23(a), plaintiffs must demonstrate that (1) other members of the class have the same or similar injury, (2) the action is based on conduct which is not unique to the named plaintiff, and (3) other class members have been injured by the same course of conduct. *Hansen v. Ticket Track, Inc.*, 213 F.R.D. 412, 415 (W.D. Wash. 2003) (*citing Hanlon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992)). "When it is alleged that the same unlawful conduct was directed at or affected both the named

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plaintiff and the class sought to be represented, the typicality requirement is usually satisfied, irrespective of varying fact patterns which underlie individual claims." *Kavu, Inc. v. Omnipak Corp.*, 246 F.R.D. 642, 648 (W.D. Wash. 2007) (*quoting Smith v. Univ. of Wash. Law Sch.*, 2 F. Supp. 2d 1324, 1342 (W.D. Wash. 1998)). Notably, the named plaintiffs' circumstances need only be "reasonably co-extensive with those of absent class members; they need not be substantially identical." *Hanlon*, 150 F.3d at 1020. "Indeed, even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories." *Baby Neal v. Casey*, 43 F.3d 48, 58 (3d Cir. 1994). As a result, "Where an action challenges a policy or practice, the named plaintiffs suffering one specific injury from the practice can represent a class suffering other injuries, so long as all the injuries are shown to result from the practice." *Id.* at 57–58.

Both B.E. and A.R. are typical of the class. Each class member has suffered the same injury of being categorically excluded from receiving medically necessary care by the WHCA Policy. Variations on how HCV manifests itself in each class member's body do not affect commonality. Regardless of individual differences, each class member shares the typical characteristic of being excluded from treatment despite prevailing clinical standards to the contrary. "Typicality refers to the nature of the claim or defense of the class representative, and not to the specific facts from which it arose or the relief sought." *Parsons v. Ryan*, 754 F.3d 657, 685 (9th Cir. 2014) *quoting Hanon v. Dataproducts Corp.*, 976 F.2d 497, 508 (9th Cir. 1992).

The Ninth Circuit's opinion in *Parsons* provides a useful analog. In that case, a class of inmates raised a constitutional challenge to the conditions of their confinement by the Arizona Department of Corrections. *Parsons*, 754 F.3d at 662–63. The allegations described issues as diverse as the provision of insufficient nutrition, confinement to a single cell with unceasing

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lighting for lengthy periods, and grossly inadequate dental care. *Id.* While all of these complaints obviously manifested themselves in individualized ways, they shared the common claim that the defendant's policies and practices were exposing the class to "substantial risk of serious harm, including unnecessary pain and suffering … and death." *Id.* Reviewing the district court's class certification order, the Ninth Circuit found that the named plaintiffs had alleged "'the same or [a] similar injury' as the rest of the putative class; they allege that this injury is a result of a course of conduct that is not unique to any of them; and they allege that the injury follows from the course of conduct at the center of the class claim." *Parsons,* 754 F.3d at 685, *quoting Hanon,* 976 F.2d at 508.

Such is the case here. Just as every inmate in *Parsons* was "highly likely to require medical [ ] care," *id.,* so too is each class member in the case *sub judice* who has HCV and a concurrent medical need to be cured. More fundamentally, the Ninth Circuit took pains in *Parsons* to observe the inmate class members were "all exposed to a substantial risk of serious harm, not that their particular experiences in the past violated the Eighth Amendment." *Parsons,* 754 F.3d at 685 n.31. B.E. and A.R. similarly describe an injury – their exclusion from DAA treatment by the WHCA Policy – that contravenes federal law and exposes each class member to a significant risk of future harm. *See* Gish Decl., ¶ 10 (describing heightened risks where HCV treatment is delayed).[2] As in *Parsons*, "[i]t does not matter that the named plaintiffs may have in the past suffered varying injuries or that they may currently have different health care needs; Rule

[2] It bears noting here that the Washington definition of "medical necessity" on which the WHCA Policy is required to rest expressly includes a "requested service which is reasonably calculated to *prevent* … or *prevent worsening* of conditions in the client that endanger life, or cause suffering or pain…." Wash. Admin. Code 182-500-0070 (emphasis added). Just as the inmates' Eighth Amendment case in chief involved a showing of unreasonable risk of future harm in *Parsons*, so too are Plaintiffs' claims here predicated on forecasting future risk they face as a result of the defendant's policy. The analogy to *Parsons* is uniquely appropriate.

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23(a)(3) requires only that their claims be 'typical' of the class, not that they be identically positioned to each other or to every class member." *Parsons v. Ryan*, 754 F.3d at 686. Plaintiffs' claims satisfy the typicality requirement of Fed. R. Civ. P. 23(a).

4. Plaintiffs and Their Counsel Are Adequate Representatives.

Under FRCP 23(a)(4), plaintiffs are responsible for answering two questions in order to illustrate their adequacy as class representatives: "(1) do the named plaintiffs and their counsel have any conflicts of interest with other class members and (2) will the named plaintiffs and their counsel prosecute the action vigorously on behalf of the class?" *Hanlon*, 150 F.3d at 1020.

B.E. and A.R. have no conflicts of interest with the class they seek to represent. Dkt. No. 7, ¶ 7; Dkt. No. 8, ¶ 9. They are each Medicaid enrollees living with HCV and in need of care under the AASLD / IDSA Guidelines, yet have been denied DAA Treatment under the WHCA Policy. Dkt. No. 7, ¶¶ 1–3; Dkt. No. 8, ¶¶ 1–3. Their interests are perfectly aligned with the absent members of the putative class.

With respect to their counsel, each of the three coordinating legal organizations seeking to represent the class have significant experience litigating on behalf of vulnerable populations of low-income medical consumers in complex matters. *See* Crewdson Decl., ¶¶ 4–5; Costello Decl., ¶¶ 4–7; Hamburger Decl., ¶¶ 3–8; Spoonemore Decl., ¶¶ 2–3.

B. The Court Should Certify a Class for Injunctive Relief Under Fed. R. Civ. P. 23(b)(2).

Certification is appropriate under Fed. R. Civ. P. 23(b)(2) so that class-wide preliminary injunctive relief may be ordered. Certification is appropriate under this provision where the defendant has "acted on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). Stated differently, certification is appropriate where injunctive or

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declaratory relief can be provided to the members of the class without engaging in a case-by-case analysis of the individual circumstances of each class member. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2558 (2011) ("The key to the (b)(2) class is 'the indivisible nature of the injunctive or declaratory remedy warranted—the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them.'").

Plaintiffs' motion for a preliminary injunction seeks the removal of the WHCA Policy based solely on cost, which excludes Medicaid enrollees with HCV because they have not suffered enough liver damage. Plaintiffs do not ask the Court to make individualized determinations of class members' medical need. Rather, plaintiffs ask the Court to strike down the WHCA Policy that ***prevents*** consideration of individual medical need, in contravention of both the prevailing standard of care, as well as state and federal Medicaid law and guidance from the Center for Medicaid and Medicare Services. In *Dunakin v. Quigley*, Judge Robart was presented with a similar claim in which "[p]laintiffs allege a systemic problem with [state agency] procedures, and they seek injunctive and declaratory relief to change [state agency]'s conduct on an agency-wide basis." *Dunakin*, 99 F. Supp. 3d at 1333, *quoting Van Meter v. Harvey*, 272 F.R.D. 274, 282 (D. Me. 2011). Granting certification, Judge Robart ruled that "[s]uch relief is appropriate respecting the whole class because if Plaintiffs' allegations prove correct, every putative class member will be entitled to the relief." *Id. See also Elkins v. Dreyfus*, 2010 WL 3947499, at *7 (W.D. Wash. Oct. 6, 2010) (where plaintiff seeks injunctive and declaratory relief that, if granted, will apply to all members of the proposed class, the requirements of Rule 23(b)(2) are "easily satisfied").

Should the plaintiffs gain the relief they seek, each member of the putative class will be entitled to uniform relief: the end of the WHCA Policy and its categorical exclusions in favor of

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a policy that properly adjudges DAA Treatment coverage based on individual medical need, prevailing clinical standards, and state and federal Medicaid law.

V. CONCLUSION

The Court should certify the proposed class, appoint B.E. and A.R. as class representatives and appoint Columbia Legal Services, The Center For Health Law and Policy Innovation and Sirianni Youtz Spoonemore Hamburger as Class counsel.

DATED: March 18, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on March 18, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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DATED: March 18, 2016, at Seattle, Washington.

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